REMARKS

Claim 103 has been amended. Claims 103-110 are pending in the present application.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 103-110 under 35 U.S.C. § 101

Claims 103-110 remain rejected under 35 U.S.C. § 101 on the ground that the claimed invention lacks patentable utility. The Office Action states:

> Applicant's arguments filed 09 April 2004 have been fully considered but they are not persuasive. The applicants point to the declaration under 37 CFR 1.132 by Randy Berka for support of utility of the claimed invention. However it is not apparent that the data in the example detailed in the declaration comprises the probes of SEQ ID NO: 4377-7401 to which the claimed invention is limited. For example, a review of Table 3 of the specification does not reveal description of probe TREMBL Q96WT5 of the declaration. As such it cannot be determined whether the data of the declaration supports a utility of the claimed invention. The applicants state that TREMBL Q96WT5 is identical to SEQ ID NO: 5814, however the declaration of Berka does not state that and until such time as the applicants establish that at least one probe of the claimed array has utility, the rejections detailed above will be maintained.

This rejection is respectfully traversed.

Dr. Randy Berka has prepared a Declaration (see attached) stating that TREMBL Q96WT5 corresponds to SEQ ID NO: 5814.

Applicants have asserted in previous Amendments of August 23, 2002, May 7, 2003, September 22, 2003, and April 6, 2004, that the claimed method using the combination of *Aspergillus oryzae* ESTs of SEQ ID NOs. 4377-7401 is supported by a substantial patentable utility.

Applicants submitted a Declaration by Dr. Randy Berka in the Amendment of September 22, 2003, where Dr. Berka disagreed with the Office Action's contention that the "claimed combination of nucleic acids is not supported by a substantial utility".

Dr. Berka described the use of a microarray of *Aspergillus oryzae* ESTs of the instant invention to study a recombinant *Aspergillus oryzae* strain (Le-1) containing a *Thermomyces lanuginosus* lipase gene and a yield- and morphologically-improved mutant (7-1) of Le-1 to understand why the recombinant strain Le-1 displayed a very pronounced "ballooning" cell state when grown under fermentation conditions and after approximately 90 hours of fermentation production of the lipase ceased, while mutant 7-1 displayed a much lower degree of ballooning and

did not stop producing lipase after 90 hours. The "ballooning" was detrimental to achieving a commercially successful fermentation process with recombinant strain Le-1 because of lipase production ceasing after approximately 90 hours of fermentation. An understanding of the genes that contributed to the "ballooning" cell state would provide information on how to cultivate a microorganism to develop a commercially successful fermentation process.

Dr. Berka demonstrated that the experiments involving a microarray of *Aspergillus oryzae* ESTs of the present invention allowed the measurement of individual transcript levels of *Aspergillus oryzae* strains which correlated to a predisposition to the onset of a particular cell state, *i.e.,* "ballooning," that was detrimental to achieving a commercially successful fermentation process, and led to the identification of genes that contribute to the "ballooning" cell state for diagnosis, prevention, or further monitoring. The information provided led to a simple solution to preventing the onset of the ballooning cell state by changing the medium composition. Moreover, the results of the study provided an explanation of why mutant 7-1 retained its lipase expression potential throughout a fermentation while strain Le-1 did not.

Applicants assert, therefore, that the claimed method using the combination of nucleic acids of *Aspergillus oryzae* ESTs is supported by a substantial patentable utility. For the foregoing reasons, Applicants submit that the rejection under 35 U.S.C. § 101 has been overcome and respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 103-110 under 35 U.S.C. § 112, First Paragraph

Claims 103-110 stand rejected under 35 U.S.C. § 112, first paragraph, on the ground that one skilled in the art would not know how to use the claimed invention since it is not supported by a substantial utility or a well established utility. This rejection is respectfully traversed.

Based on Applicants' arguments in Section I, Applicants assert that one skilled in the art would know how to use the claimed invention because it is supported by a substantial utility.

For the foregoing reason, Applicants submit that the rejection under 35 U.S.C. § 112, first paragraph, has been overcome and respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claims 103-110 under 35 U.S.C. § 112, Second Paragraph

Claims 103-110 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because they are not limited to a combination consisting of SEQ ID NO: 4377-7401, which is the elected combination of sequences.

Applicants have amended claim 103 to recite in part: "...an array of *Aspergillus oryzae* ESTs of SEQ ID NOs. 4377-7401..."

For the foregoing reason, Applicants submit that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome and respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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Robert L. Starnes, Ph.D.
Reg. No. 41,324
Novozymes Biotech, Inc.
1445 Drew Avenue
Davis, CA 95616-4880
(530) 757-4715